Appln. No. 10/643,319 Amendment responsive to November 4, 2005 Office Action

Amendments to the Claims:

This listing of claims will replace all prior versions, and listing, of claims in the application.

Listing of Claims:

Claims 1 - 42 (Canceled)

Claim 43 (Original): A pharmaceutical formulation for oral administration of insulin comprising a particulate pharmaceutical substrate having an application of an insulin coating, wherein the particulate pharmaceutical substrate is free of a polysaccharide.

Claim 44 (Original): The oral pharmaceutical formulation of claim 43, wherein the insulin coating includes a material selected from the group consisting of coating agents, controlled release agents, sustained release agents, pharmaceutical excipient agents, and combinations thereof.

Claim 45 (Original): The oral pharmaceutical formulation of claim 44, wherein the agent is selected from the group consisting of colorants, film-forming polymers, plasticizers, surfactants, permeation enhancers, buffering agents, dispersions of ethyl cellulose, coating lacquers, pigments, and combinations thereof.

Claim 46 (Original): The oral pharmaceutical formulation of claim 43, wherein the insulin comprises an insulin load on the substrate ranging from about 0.1% to about 30% weight/weight.

Claim 47 (Original): The oral pharmaceutical formulation of claim 43, wherein the substrate is selected from the group consisting of a calcium material, cellulose, and combinations thereof.

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Claim 48 (Original): The oral pharmaceutical formulation of claim 47, wherein the calcium

material is selected from the group consisting of calcium carbonate, calcium citrate, dibasic

calcium phosphate dihydrate, monobasic calcium phosphate, tribasic calcium phosphate,

anhydrous dibasic calcium phosphate, and combinations thereof.

Claim 49 (Original): The oral pharmaceutical formulation of claim 43, further including another

coating.

Claim 50 (Original): The oral pharmaceutical formulation of claim 49, wherein another coating

is under the insulin coating, over the insulin coating, or a combination thereof.

Claim 51 (Original): The oral pharmaceutical formulation of claim 49, wherein the other coating

comprises a material selected from the group consisting of coating agents, controlled release

agents, sustained release agents, pharmaceutical excipient agents, and combinations thereof.

Claim 52 (Original): The oral pharmaceutical formulation of claim 51, wherein the agent is

selected from the group consisting of colorants, film-forming polymers, plasticizers, surfactants,

permeation enhancers, buffering agents, dispersions of ethyl cellulose, coating lacquers,

pigments, and combinations thereof.

Claim 53 (Original): The oral pharmaceutical formulation of claim 43, wherein the particulate

pharmaceutical substrate having an application of an insulin coating is encapsulated in a gelatin

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capsule or is compressed into a tablet.

Claim 54 (Canceled)

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Claim 55 (Original): An oral pharmaceutical formulation of insulin comprising a particulate dibasic calcium phosphate dihydrate pharmaceutical substrate having an application of an insulin coating, wherein:

- (a) the insulin is present in a load on the substrate ranging from about 0.1% to 30% weight/weight, and
- (b) the substrate is free of a polysaccharide and has been coated with a permeation enhancer.

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